REMARKS

Status Of The Claims

Claims 1-12 are pending in the application.

Claims 4-6 and 10-12 stand withdrawn from consideration due to a restriction requirement.

Claims 1-3 and 7-9 stand rejected.

The Rejection Under 35 U.S.C. 103(a)

The Examiner has rejected claims 1-3 and 7-9 under 35 U.S.C. 103(a) as being unpatentable over Reynolds (WO 98/40406) in view of Muhler (US 3,590,120). The Examiner holds as follows:

> Reynolds discloses a sugar-free chewing gum including gum base and 1-50% CPP-ACP, which promotes dental hygiene and remineralization of tooth enamel in individuals who chew the gum. It would have been obvious to include 1-6% sodium bicarbonate in the chewing gum of Reynolds in order to remove dental plaque from the teeth of individuals chewing the gum since 1-5% sodium bicarbonate is a conventional dental plaque removal agent in chewing gum as evidenced by Muhler (col. 2, lines 47-58) and since dental hygiene is a goal which Reynolds seeks to achieve for individuals chewing his gum.
>
> Applicants claimed range of gum base is conventional for chewing gums.
>
> Applicants' arguments with respect to claims 1-3 and 7-9 submitted January 7, 2002 have been considered but are moot in view of the new ground(s) of rejection.

The Examiner is respectfully requested to reconsider and withdraw the rejection for the reasons as follow.

Applicants claims are drawn to low moisture chewing gums comprising, by weight, from about 10% to 95% gum base, from about 0.1% to 15% sodium bicarbonate, and from about 0.01% to about 30% of CPP-ACP.

Reynolds (WO 98/40406), concerns CPP-ACP complexes and their use as, inter alia, anti-caries agents. Reynolds teaches that the complex can be incorporated into oral compositions such as those listed at pages 5 and 6, namely, toothpaste, toothpowder, mouthwashes, troches, chewing gum, dental pastes, gingival massage creams, gargle tablets, dairy products and other foodstuffs. Reynolds does not teach sodium bicarbonate in chewing gum.

Muhler (US 3,590,120) teaches chewing gums which contain up to 5% of a chemical agent such as sodium bicarbonate ($NaHCO_3$) to remove dental plaque. Other dental cleaning and polishing agents such as a blend of fine and coarse sized ziconium silicates are used together with the sodium bicarbonate.

Applicants cite and discuss the benefits of both the Reynolds (WO 98/40406) and Muhler (US 3,590,120) technologies in their specification but further point out that:

> While it would be very desirable to combine in one delivery system the plaque reduction and tooth whitening benefits of sodium bicarbonate with the remineralization and strengthening of teeth provided by CPP-ACP, it is known that sodium bicarbonate will react with calcium phosphate to form calcium carbonate. Combining sodium bicarbonate with CPP-ACP, would be expected to precipitate calcium carbonate thereby diminishing the supply of calcium ions and concomitantly diminish the efficacy of CPP-ACP. A combination of the two dental care components in a system such as traditional oral rinses and pastes, would result in a diminishing or deactivation of the remineralization efficacy of the CPP-ACP.

This is a fact which one skilled in the dental art would consider together with the other facts in the case. Whereas it may be desirable to combine a remineralizing material together with a whitening agent in a dental preparation, one would not be led to combine a soluble calcium compound with a bicarbonate salt in that the only obvious result would be a diminishing of the efficacy of both.

In the present invention applicants have provided a means for overcoming the problem of combining the ingredients in an oral delivery system. Applicants successfully combine sodium bicarbonate and a soluble calcium containing compound in a low moisture chewing gum. The solid delivery form, chewing gum, prevents the two actives (CPP-ACP and sodium bicarbonate) from admixing and thereby remain stable over time. The use of a low moisture gum, i.e., one containing less than 2% moisture, further enhances that storage stability.

Neither Reynolds not Muhler suggests that sodium bicarbonate and a soluble calcium containing compound be combined. The teaching of Reynolds gives no implication that one could use sodium bicarbonate in a chewing gum together with the CPP-ACP taught therein. Reynolds teaches very little concerning chewing gum. Reynolds leads neither by teaching nor example to an inference of the claimed invention. Mueller does not suggest the combination. Mueller was only concerned with the combination of sodium bicarbonate with insoluble abrasives such as the ziconium silicate abrasives optionally with other insoluble abrasives such as calcium phosphate compounds or insoluble materials as calcium carbonate or talc or the like. Mueller teaches that the main benefit is provided by the presence of the silicates. Muhler's specific use of insoluble abrasives does not lead to the claimed invention.

Applicants submit that the Examiner's position does not take into consideration all that would be taken into consideration by one skilled in the art, i.e., it does not

consider the fact of the chemical reactivity of the two compounds. The expected chemical reactivity would lead away from the use of the two in a dental delivery system. Nothing in the cited art overcomes this predicted result.

It is only in hindsight reconstruction that applicants invention is obvious. In view of the above, the rejection of claims 1-3 and 7-9, as amended, under 35 U.S.C. 103(a), should be withdrawn.

Conclusion

In view of the above applicants believe all of the claims in this application are in condition for allowance. If any questions remain, the resolution of which would be advanced by conference (telephonic or personal) with applicants' agent, the Examiner is invited to contact said agent at the telephone or the fax number noted below.

Respectfully submitted,
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